therapeutics letter©

THERAPEUTICS INITIATIVE Evidence Based Drug Therapy

Direct To Consumer Advertising:

Finasteride for male pattern hair loss

Case: Mr. Jones (26 years old) comes in to see you about a cough he has had for 3-4 weeks. You've just finished listening to his chest and reassured him that it's the aftermath of a viral infection. He asks you, "By the way, I'm wondering about this pill I saw advertised. I think the name was Propecius. I've been noticing my hair seems to be thinning on top lately, and I'd like to try it."

Does this sound familiar?

Clinicians are increasingly feeling the impact of direct-to-consumer advertising of prescription drugs (DTCA). While advertising prescription drugs directly to consumers is not allowed in Canada, patients see newspaper reports, US ads, ads directed at health professionals, etc. In Canada, the average practicing physician can expect to get 10 specific drug requests per week, some of which would be for advertised drugs. In the United States DTCA appears to increase sales (see insert below).

What should clinicians do in this situation?

Let's explore the issue using one of the products most advertised to consumers, a drug for male pattern hair loss, finasteride (Propecia®).

What questions should you answer before writing a prescription?

• **Does this patient fit the drug's indications?** Propecia® is for a cosmetic effect in young men (18-41 yrs) who have mild to moderate scalp hair loss of the vertex or anterior mid scalp.[2] It does not benefit men with hair loss at the temples or those who are completely bald.[3] It is not indicated for use in women or children.[2, 4]

• **Does the patient have a realistic idea of the drug's effectiveness?** Three papers summarize 5 randomized controlled trials in men between the ages of 18 and 41 years.[5-7] When finasteride was compared to placebo using macrophotographs of 1-inch diameter circles, hair counts increased by 12% over baseline at l year ($p < 0.00l$).[5] The patient questionnaire revealed that finasteride improved the appearance of the hair in 58% of patients as compared to placebo 35%, ABI* = 23% [95% CI* 18-28], NNT* = 4 for 1 year.

DTCA in the United States in 1999[1] (in US$)

Advertising

- Pharmaceutical companies spent $1.8 billion on DTCA, a 40% increase over 1998.
- $1.1 billion was spent on television ads, a 70% increase over 1998.
- 41% of DTCA spending was concentrated on ten products, among them loratidine (Claritin®, $137 million), **finasteride (Propecia®, $100 million)**, sildenafil (Viagra®, $94 million), omeprazole (Prilosec®, $80 million), and orlistat (Xenical®, $76 million).

Sales

- The 25 top-selling DTCA drugs accounted for 40.7%, or $7.2 billion, of the overall $17.7 billion (19%) increase in drug sales (retail) in 1999 over 1998.
- Doctors wrote 34.2% more prescriptions in 1999 than in 1998 for the top 25 DTCA drugs. Doctors wrote only 5.1% more prescriptions for all other prescription drugs.

Mailing Address: Therapeutics Initiative
The University of British Columbia
Department of Pharmacology & Therapeutics
2176 Health Sciences Mall
Vancouver, BC Canada V6T 1Z3

Tel.: (604) 822•0700
Fax: (604) 822•0701
E-mail: info@ti.ubc.ca
Web: www.ti.ubc.ca
(all Therapeutics Letters, Course Information)

Overall satisfaction with hair occurred in 39% of finasteride group as compared to 22% of placebo group, ABI = 17% [95% CI 12-21], NNT = 6 for 1 year.[5]

• What other options are available? Topical minoxidil (Rogaine®) is available over-the-counter in 2% strength and by prescription in 5% strength. Finasteride has not been compared to minoxidil. Other options include surgical hair implants or hairpieces.

• What are the harms and risks of taking this drug? In the randomized controlled trials 4.2% of the finasteride group reported one or more adverse sexual experiences (decreased libido, erectile dysfunction, or ejaculation disorder) as compared to 2.2% of the placebo group, ARI* = 2.0%, NNH* = 50 for 1 year ($p < 0.05$).[5] Long-term adverse effects are unknown at this time.

• How long will I have to prescribe it? Continued treatment is needed to maintain benefit; **if treatment is stopped, any benefit will be lost within 6 to 12 months.**[3, 5]

• How will I know that it is working? It is difficult to be certain in any individual case whether the drug is working. If the patient is not achieving the desired cosmetic effect in 6 to 12 months there is no reason to continue.

• What other facts should I know about this drug? Finasteride is also prescribed at a higher dose under the trade name Proscar® for the treatment of symptoms of benign prostatic hypertrophy, because of its effect to decrease prostate volume (see Therapeutics Letter #19).

The dose for male baldness (1 mg/day) and doses as low as 0.2 mg/day reduce dihydrotestosterone serum concentrations by approximately 70%, increase testosterone serum concentrations by about 20%, and variably decrease concentrations of prostatic specific antigen.[3, 5, 6, 8] The clinical significance and long-term consequences of these effects is unknown at this time.

Any contact with the drug is contraindicated in women who are pregnant or may become pregnant as the drug can cause abnormalities of the genitalia in male fetuses.

• What are my legal liabilities if I give in to patient pressure and prescribe it? No different than for any other drug you prescribe.

• What is it going to cost? Finasteride, 1 mg tablets, for male pattern baldness, average daily cost $1.60. Finasteride, 5 mg tablets, for symptoms of prostatic hypertrophy, average daily cost $1.70.

What happens to a company when the DTCA is deemed to be misleading?

Two ads for Propecia® in Time Magazine were found to be misleading by the Division of Drug Marketing, Advertising and Communications at the US FDA. These ads stated "One day science will create a pill for hair loss: That day is today." And "Starting today, you need not face the fear of more hair loss". In both cases the FDA found the ads claimed a broader benefit than had been demonstrated and advised the company to immediately discontinue the ads. No other action was taken.

Conclusions

• DTCA appears to increase drug sales and adds to the pressure on busy clinicians.

• Before yielding to this pressure, physicians must be able to convey to the patient in a meaningful way:

- **the known benefits** (e.g. 6 men have to be treated for one year with finasteride for 1 to be satisfied with the appearance of his hair).
- **the known harms** (e.g. 1 in 50 men treated with finasteride for l year will have an adverse sexual experience).
- **the unknown risks** (e.g. long-term finasteride therapy is necessary to maintain benefit and long-term effects are unknown at this time).

*** Abbreviations used in text:**

ABI = Absolute Benefit Increase
NNT = Number Needed to Treat to Benefit one Patient
ARI = Absolute Risk Increase
NNH = Number Needed to Treat to cause one Harmful event
CI = Confidence Interval

References

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This Letter contains an assessment and synthesis of published (and whenever possible peer-reviewed) publications up to March 2001. We attempt to maintain the accuracy of the information in the Therapeutics Letter by extensive literature searches and verification by both the authors and the editorial board. In addition this Therapeutics Letter was submitted for review to 55 experts and primary care physicians in order to correct any inaccuracies and to ensure that the information is concise and relevant to clinicians.